

Application No.: 10/533,398  
Amdt dated: December 22, 2006  
Reply to Office action of September 22, 2006

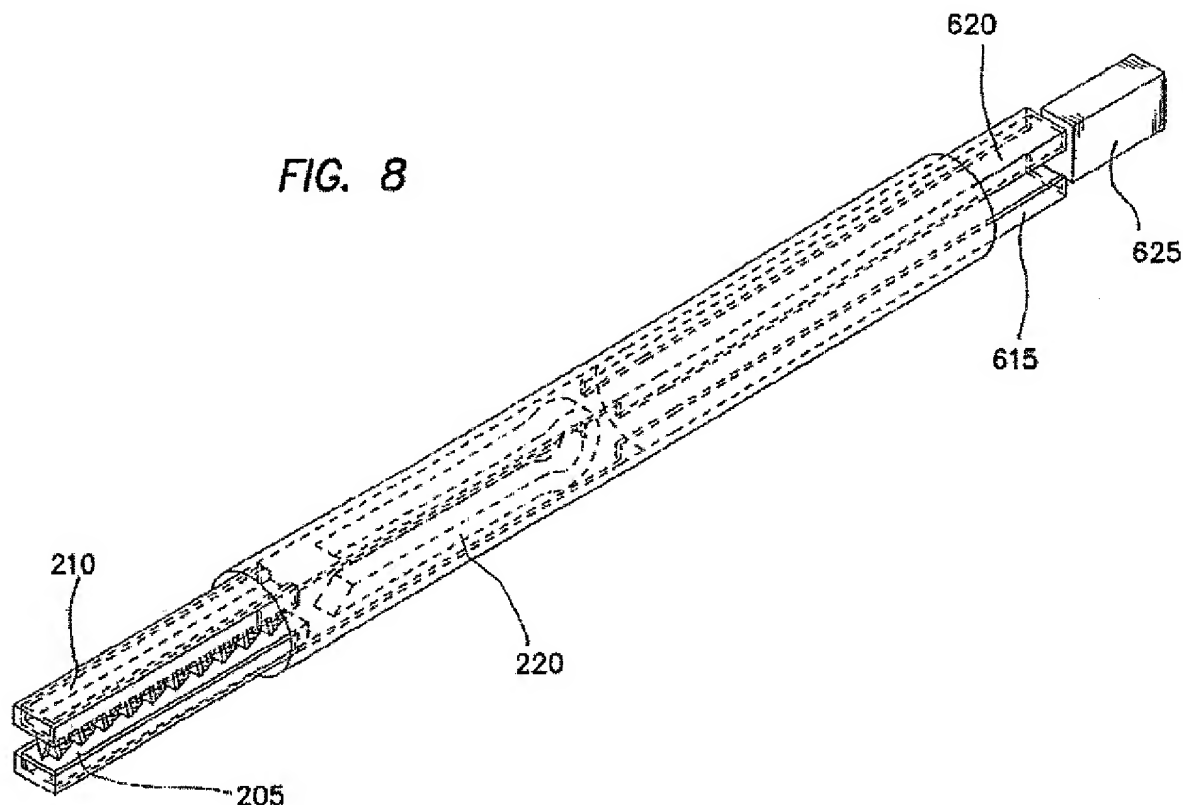
### **REMARKS**

This amendment is in response to the Office action mailed on September 22, 2006. Claims 29-38 are canceled without prejudice and/or disclaimer. Claims 1-21 and 39-43 are withdrawn. Claim 22 and 26 has been amended. New claims 48-49 have been added. Claims 1-28 and 39-49 are pending in the application.

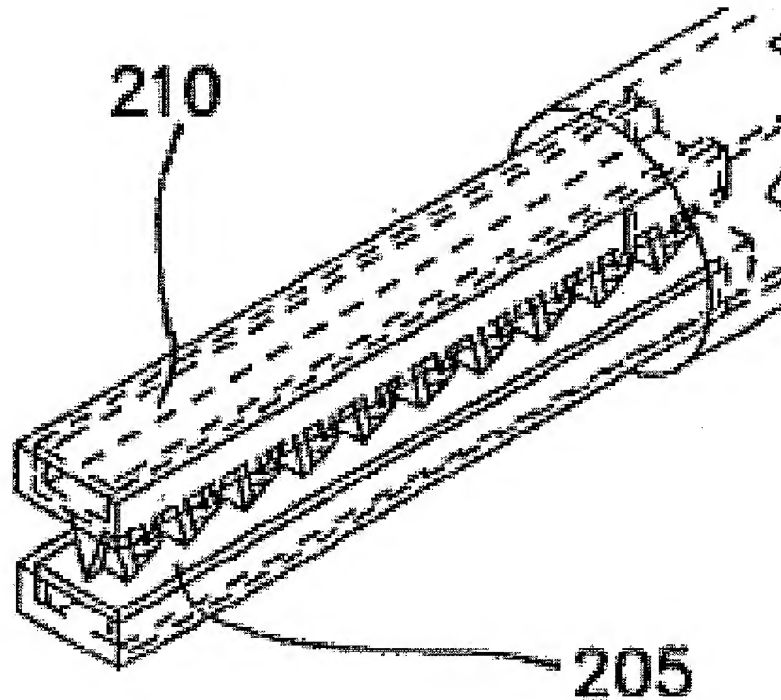
### **Drawings**

On page 2 of the Action, the drawings are objected to under 37 CFR 1.83(a). The action further states that the handle (Claim 22), the plurality of slots in each of the opposed jaws (Claim 29), and the first slot of one jaw and second slot of the other jaw (Claims 45-47) must be shown or the feature(s) canceled from the claim(s). Applicant respectfully traverses the objection. Regarding the handle (Claim 22), Figure 5A provides an example of such a handle 180. Applicant notes that Figure 5A was not specifically identified as of the elected Invention I, Species A as identified by the previous Action and the subsequent Applicant's response. Accordingly, as it appears such a feature of the invention must be shown, Applicant submits that Figure 5A should be consider drawn to the Invention I, Species A. If, however, the Examiner believes a different election/restriction requirement is now required and/or selection of claims, Applicant reserves the right to change/traverse the election of species and claims directed thereto.

Regarding the first slot of one jaw and second slot of the other jaw (Claims 45-47), Figure 8 provides an example of this feature. The figure is provided below for ease of reference.



The "one jaw" is identified by reference numeral 620 and the "other jaw" is identified by reference numeral 615. A series of dashed lines extend from the proximal end of the "one jaw" near the sliding member 625 towards the distal end of the "one jaw". The dashed lines outline the "first slot" of the "one jaw". Separate from the series of dashed lines, but also represented in dashed lines is an outline of securing member 220. Similarly, the outline of the tissue-engaging member 210 is partially represented in dashed lines separate from the series of dashed lines representing the "first slot". An enlarged version of Figure 8 of the distal portion of the "one jaw" is shown below to assist in highlighting the separate "first slot" from the tissue-engaging member 210 and the separate "second slot" from the tissue-engaging member 205.



Similar to the jaw 620, the "other jaw" 615 has a series of dashed lines extending from the proximal end of the "other jaw" near the slider 625 towards the distal end of the "other jaw". The dashed lines outline the "second slot" of the "other jaw". Again, separate from the series of dashed lines, but also represented in dashed lines is an outline of securing member 220. Similarly, the outline of the tissue-engaging member 205 is partially represented in dashed lines separate from the series of dashed lines representing the "second slot".

Applicant notes that Figure 8 was not specifically identified as of the elected Invention I, Species A as identified by the previous Action and the subsequent Applicant's response. Accordingly, as it appears such a feature of the invention must be shown, Applicant submits that Figure 8 should be consider drawn to the Invention I,

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Species A. If, however, the Examiner believes a different election/restriction requirement is now required and/or selection of claims, Applicant reserves the right to change/traverse the election of species and claims directed thereto.

Regarding the plurality of slots in each of the opposed jaws (Claim 29), to expedite prosecution, claim 29 has been canceled without prejudice. In view of the above remarks, reconsideration and withdrawal of the objection to the drawings are respectfully requested.

### **Specification**

On page 3 of the action, the specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. The action further indicates that Claims 45 through 47 are not fully supported by the specification. Page 15 Lines 10-13 suggest the slots disclosed in the claims 45 through 47, but there is no description of how the slots operably receive the tissue engaging members. Beyond the description noted in the action on page 15, lines 10-13, as noted above, in reference to the drawings, Figure 8 shows a slot in the jaw 620 operably receiving a tissue engaging member 210. Figure 8 also shows a slot in the jaw 615 operably receiving a tissue engaging member 205. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

### **Claim Rejections – 35 USC § 112**

On page 4 of the action, claims 29, 30 and 45-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enable requirement. Applicant respectfully traverses this rejection. Regarding claim 29 and 30, however, these claims are canceled without prejudice to expedite prosecution and not in view of the rejection.

The action on page also indicates that the "first and second slots as disclosed in claims 45-47 are lacking similar descriptions. There is no description of how the tissue engaging member would be secured by a slot in the jaws, and there is no description of

where the slot is located on the jaw or what it looks like. The drawings show no evidence of a slot, and therefore, are of no help to the Examiner.” However, as previously noted above regarding the specification and drawings, Figure 8 shows a slot in the jaw 620 operably receiving a tissue engaging member 210. Figure 8 also shows a slot in the jaw 615 operably receiving a tissue engaging member 205. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

The action also indicates that the Examiner has concluded that any portion of the jaw that is capable of holding or retaining the medical device or staple-clip will be considered a slot. As such, new claims 48-49 recite that a first jaw holds a tissue engaging member, e.g., member 210, of a staple-clip, a second jaw holds a tissue engaging member, e.g., member 205, of the staple-clip.

#### **Claim Rejections – 35 USC § 102**

On page 5 of the action, claims 22-30 and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Hart et al. (US 6,139,555). Applicant respectfully traverses the rejection. Claim 22 as amended recites that a sliding member is operably connected within the elongate shaft to advance the securing member of a staple-clip over the first and the second tissue-engaging members of the staple-clip after closure of the jaws. Hart et al. does describe in col. 9, lines 29-38, that when “supplied with a plurality of clips 24 the second actuating mechanism 56 advances the proximal most clip 24 distally which in turn advances the plurality of clips 24 such that the distal most clip 24 is advanced or moved forwardly into the guide slots 38 of the jaw members 30. In a preferred embodiment, the second actuating mechanism 56 includes an elongated push rod 58 which extends substantially coaxially through the inner member 32 and contacts at least one clip 24 at its base or distal end.” As such, Hart et al. describes an actuating mechanism 56 advancing a clip and not advancing a securing member of a staple-clip over a first tissue-engaging member of the “same” staple-clip and a second tissue-engaging member of the “same” staple-clip as provided in claim 22. Thus, Hart

et al. cannot anticipate claim 22.

Since claims 23-28 and 44-47 depend from an associated independent claim 22 and thus incorporate the features recited in the corresponding claim and contain additional limitations that, when considered as a whole are patentably distinguishable over the references of record, claims 23-28 and 44-47 are believed to be patentable.

Also, claim 24 recites that the first and second tissue-engaging members are applied to the jaws either manually or automatically. In reference to claim 24, the action on page 6 indicates "(Fig 4)". As described in col. 5, lines 15-17, Hart et al. describe that "FIG. 4 is a cross-sectional view illustrating the clip applier as depicted in FIG. 3 shown with a clip inserted into the jaw members." As such, a clip is shown in Hart et al. but not first and second tissue-engaging members of the staple-clip being applied to the jaws either manually or automatically as provided in the claims and thus Hart et al. cannot anticipate claim 24.

Furthermore, claim 26 as amended recites that the first and the second tissue-engaging members and the securing member are introduced to a surgical site in an un-assembled condition through a small port or trocar with the first and second tissue-engaging members and securing member being three separate components in the un-assembled condition. In reference to claim 26, the action on page 7 indicates (Col 2 Line 22). In col. 2, lines 19-22, Hart et al. describe that by "using surgical clips that are generally pre-compressed, the overall diameter or width of the elongate outer body may be minimized in order to facilitate insertion through a trocar." However, Hart et al. does not describe that the first and second tissue-engaging members and securing member are three separate components in the un-assembled condition as recited in claim 26. Thus, Hart et al. cannot anticipate claim 26.

Moreover, claim 27 recites that the sliding member operates to urge the securing member forward and over the first and second tissue-engaging members to secure the medical device. The action indicates "(inherent, see Col. 3 Line 25)". As described in col. 3, lines 23-27, Hart et al. describes that in "yet another aspect of the

present invention, a second actuating mechanism is coupled to the proximal end of the elongate outer body. This second actuating mechanism is coupled to a push rod which extends substantially coaxially through the outer body to contact the surgical clip. Distal movement of the second actuating mechanism by a surgeon forces a clip distally from within the outer body and into the guide slots of the jaw members.” As such, Hart et al. does describe a second actuating mechanism advancing a clip, but does not describe advancing a securing member of a staple-clip over a first tissue-engaging member of the “same” staple-clip and a second tissue-engaging member of the “same” staple-clip as provided in claim 27. Thus, Hart et al. cannot anticipate claim 27. Accordingly, in view of the above remarks, reconsideration and withdrawal of the rejection is respectfully requested.

New claims 48-49 also describe various aspects of the invention that are not described or suggested by the cited references. For example, claim 48 provides a sliding member operably connected within the elongate shaft to advance a securing member of a staple-clip over a first tissue-engaging member of the staple-clip and a second tissue-engaging member of the staple-clip after closure of the jaws, the sliding member separable from the securing member of the staple-clip and the first and second tissue-engaging members of the staple-clip with the securing member separable from the first and second tissue-engaging members; wherein a first jaw of the pair of opposed jaws is arranged to hold the first tissue-engaging member of the staple-clip, the first jaw being separable from the first tissue-engaging member of the staple-clip; and a second jaw of the pair of opposed jaws is arranged to hold the second tissue-engaging member of the staple-clip, the second jaw being separable from the second-tissue engaging member of the staple-clip. Claim 49 provides that the first jaw of the pair of opposed jaws holds the first tissue engaging member of the staple-clip without the securing member of the staple-clip and a first jaw of the pair of opposed

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jaws holds the second tissue engaging member of the staple-clip without the securing member of the staple-clip.

Applicant also notes that as provided in claims 48-49, elongate shaft 605, jaws 615, 620 and sliding member 625 are shown for example in Figures 12A-B of the elected invention and species and further in the written description on page 12, line 9 to page 13, line 23. Accordingly, new claims 48-49 are believed readable on the elected invention and species. If, however, based on this amendment the Examiner believes a different election/restriction requirement is required and/or selection of claims, Applicant reserves the right to change/traverse the election of species and claims directed thereto.

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### **Conclusion**

In view of the foregoing remarks, it is respectfully submitted that this application is in condition for allowance. Accordingly, reconsideration of the application and allowance of claims 1-28 and 39-49 are respectfully requested. Applicant also respectfully submits that the features, e.g., elongate shaft 605, jaws 615, 620, and sliding member 625, depicted in figures 8, 12A-18 are merely exemplary and/or illustrative and does not disavow any claim scope or define any elements or terms in the claims in such a way other than as recited or provided in the claims and their equivalents. Likewise, any characterization of the features, e.g., elongate shaft 605, jaws 615, 620, and sliding member 625, depicted in figures 8, 12A-18 in relation to the claims are merely exemplary and/or illustrative and thus Applicant does not disavow any claim scope or specially define any elements or terms in the claims in such a way other than as recited or provided in the claims and their equivalents. If the Examiner should have any remaining questions or objections, a telephone interview to discuss and resolve these issues is respectfully requested.

Sincerely,

APPLIED MEDICAL RESOURCES

BY



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